

Sustainability Assessment of product life cycles – An introduction

08.11.2013

Janssen Pharmaceutica NV

PDMS – Technical Operations - EHS²



In collaboration with the **Ghent University**

*Department of Sustainable Organic
Chemistry and Technology*



Agenda



Agenda

- Introduction - Sustainability
- Life Cycle Assessment (LCA)
- Past, current and future LCAs
- One step ahead – EU Prospects

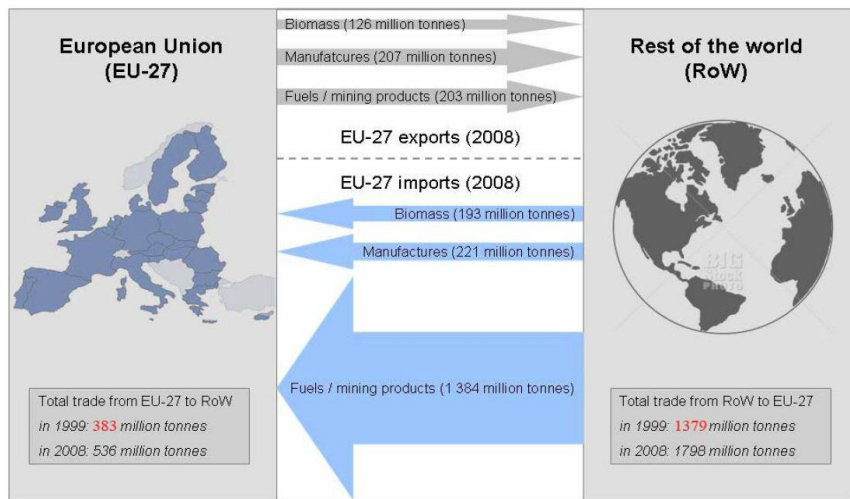
Introduction - Sustainability



Introduction: Sustainability

- What is sustainability? Brundlandt, Rio, Triple bottom line
Elkington, SLCA, LCA, LCC + FIGUUR

Our external environment



Official Journal of the European Union



English edition

Legislation

Contents

II Non-legislative acts

RECOMMENDATIONS

2013/179/EU:

★ Commission Recommendation of 9 April 2013 on the use of common methods to measure and communicate the life cycle environmental performance of products and organisations (1) ...

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Legislation
L 124

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Innovative Medicines Initiative



i-CLEANTECH
VLAANDEREN
enabling the future

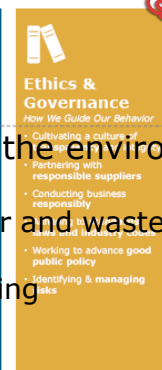


**R&D
Programs**



EARTHWARDS™ strives to improve the environmental performance of a product by:

- Reducing materials, energy, water and waste
- Utilizing safer chemicals
- Developing more efficient packaging
- Driving innovation



**J&J
Janssen**

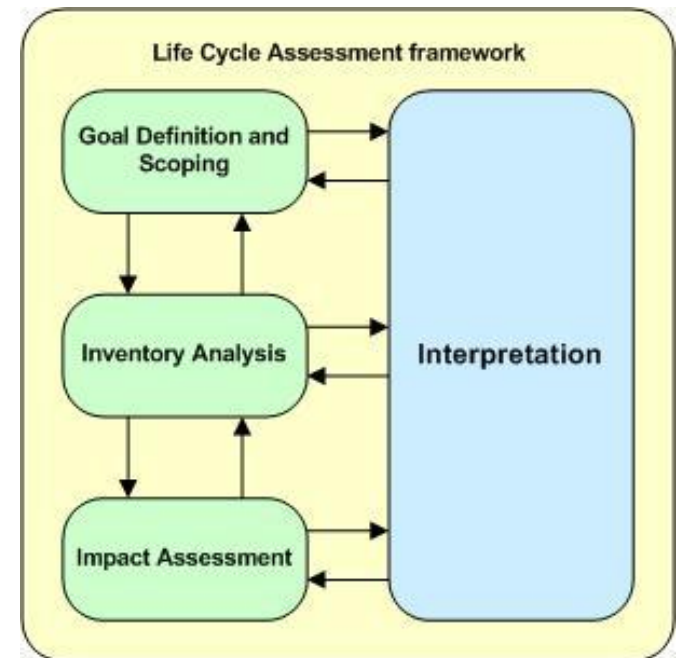


Life Cycle Assessment (LCA)



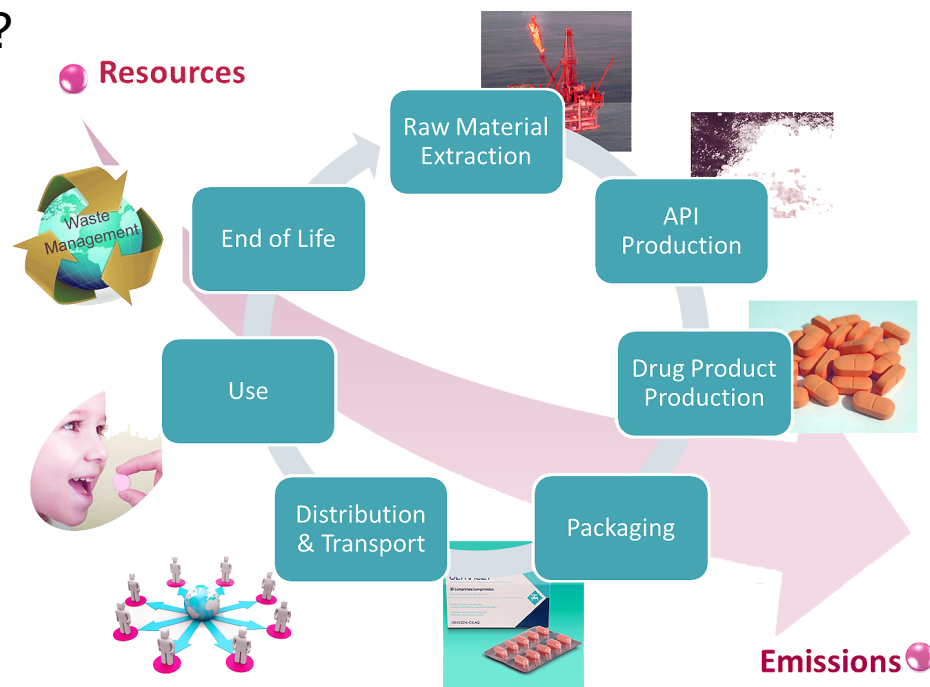
Life Cycle Assessment

- Assessment of the potential environmental impact of a given product or service within the production chain and throughout its lifespan.
 - Goal and Scope Definition
 - Life Cycle Inventory (LCI)
 - Life Cycle Impact Assessment (LCIA)
 - Interpretation



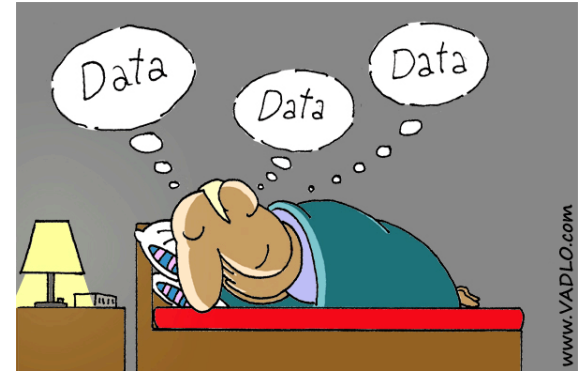
Life Cycle Assessment – Setting the Goal and Scope

- Functional Unit (FU)
- System boundaries (what to take into account)
- What impacts should be considered?
- Assumptions & limitations
- What scenarios?



Life Cycle Assessment – Inventory modeling

- Most time-consuming step
- DATA MANAGEMENT to reduce cost of LCA
- PLC → MES → SAP



Innovation

Life Cycle Assessment – Impact assessment

1. Classification – up to 18 impact categories



1 kg CO₂, 1 kg CH₄, 1 kg CFC-113



What impacts should you consider in protecting human health, ecosystem quality and natural resources?

2. Characterization

1 kg CO₂-eq

6540 kg CO₂-eq

20 kg CO₂-eq

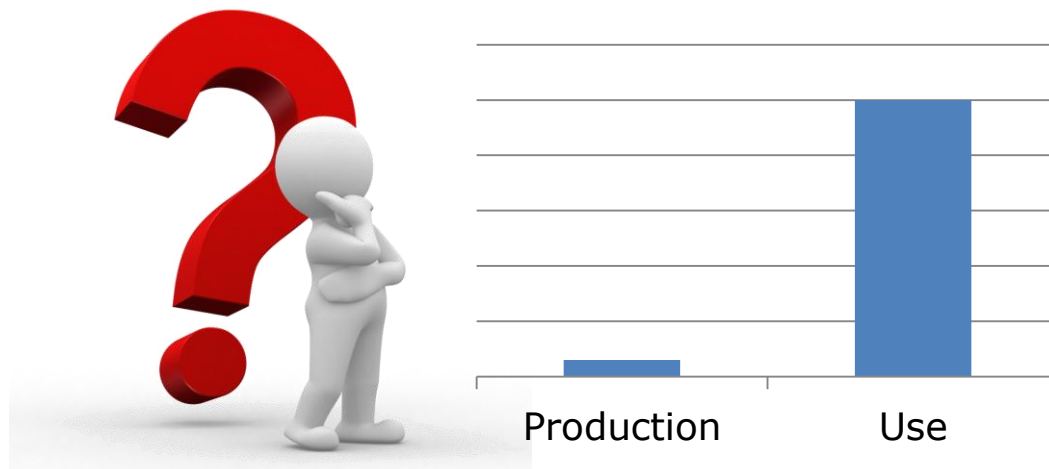


6561 kg CO₂-eq

ionising radiation (IR)
water depletion (WD)
mineral resource depletion (MRD)
fossil fuel depletion (FD)
terrestrial acidification (TA)
marine ecotoxicity (MET)
urban land occupation (ULO)
agricultural land occupation (ALO)
photochemical oxidant formation (PO)
particulate matter formation (PMF)
human toxicity (HT)
freshwater eutrophication (FE)
climate change (CC)
freshwater ecotoxicity (FET)
natural land transformation (NL)
terrestrial ecotoxicity (TET)
freshwater eutrophication (ME)

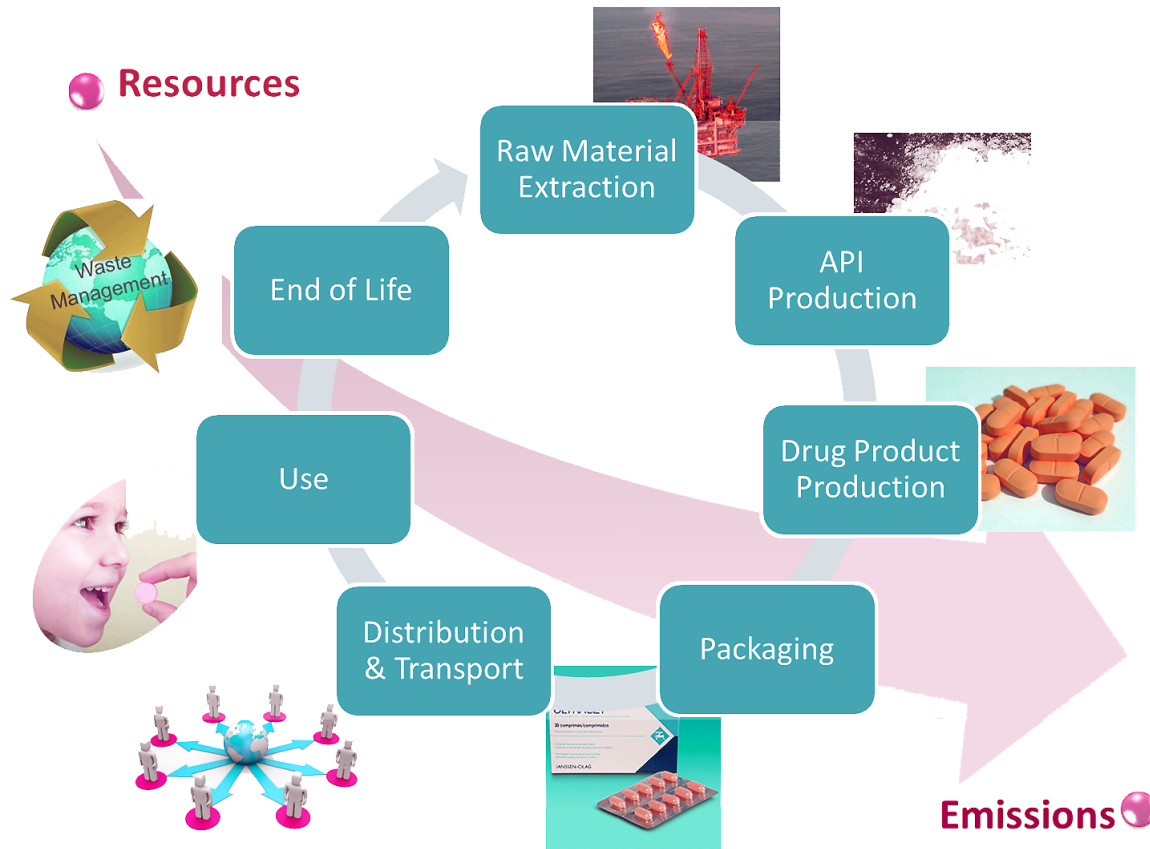
Life Cycle Assessment – Interpretation

- Most important step
- Life Cycling Thinking (LCT), Life Cycle Perspective (LCP)
- Link back with scope setting
- Sensitivity analysis, uncertainty analysis needed?



Driver of industrial production/consumption: Resources

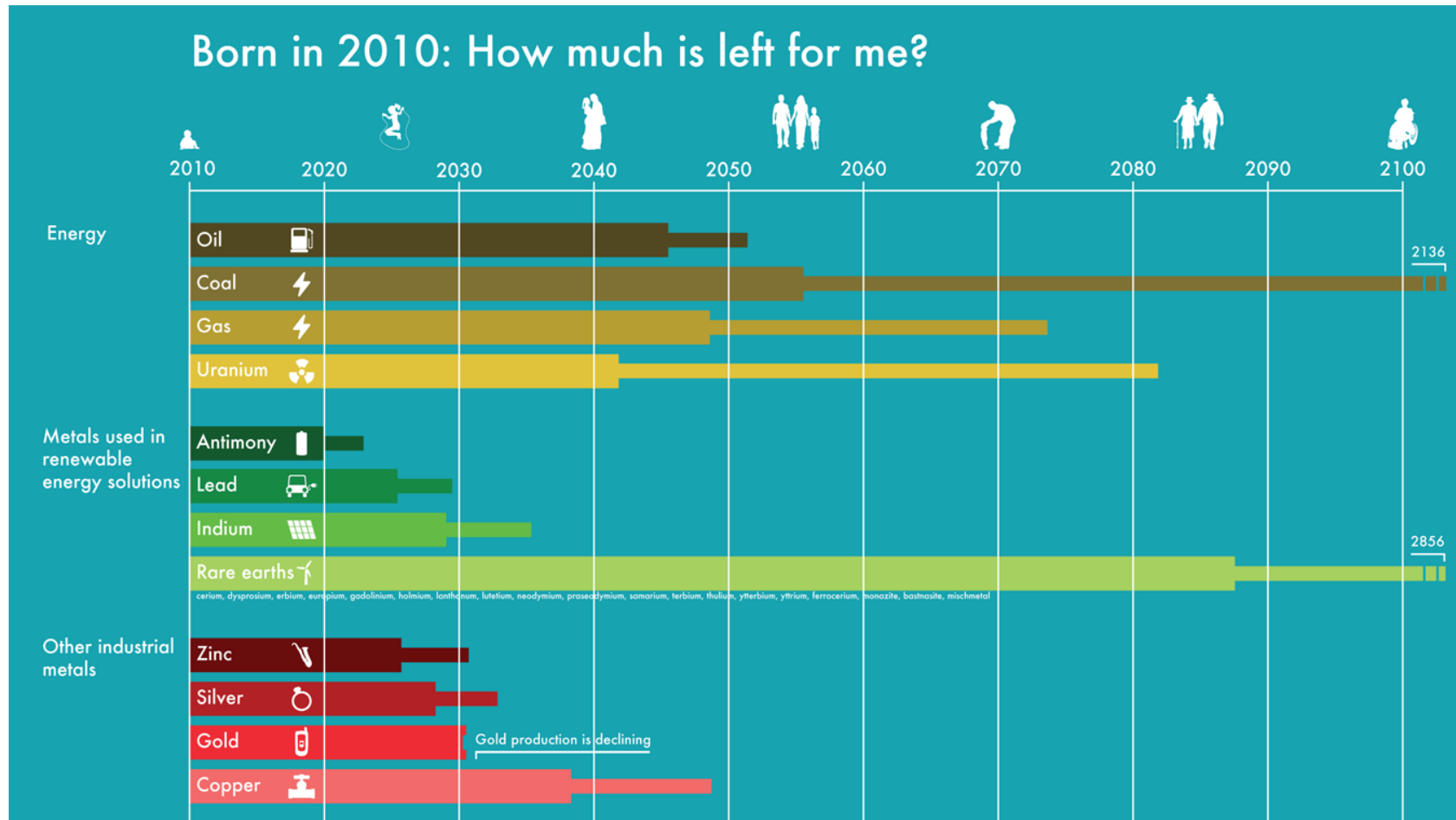
- 3 interactions with the natural environment: resources, emissions, toxicity



Driver of industrial production/consumption: Resources

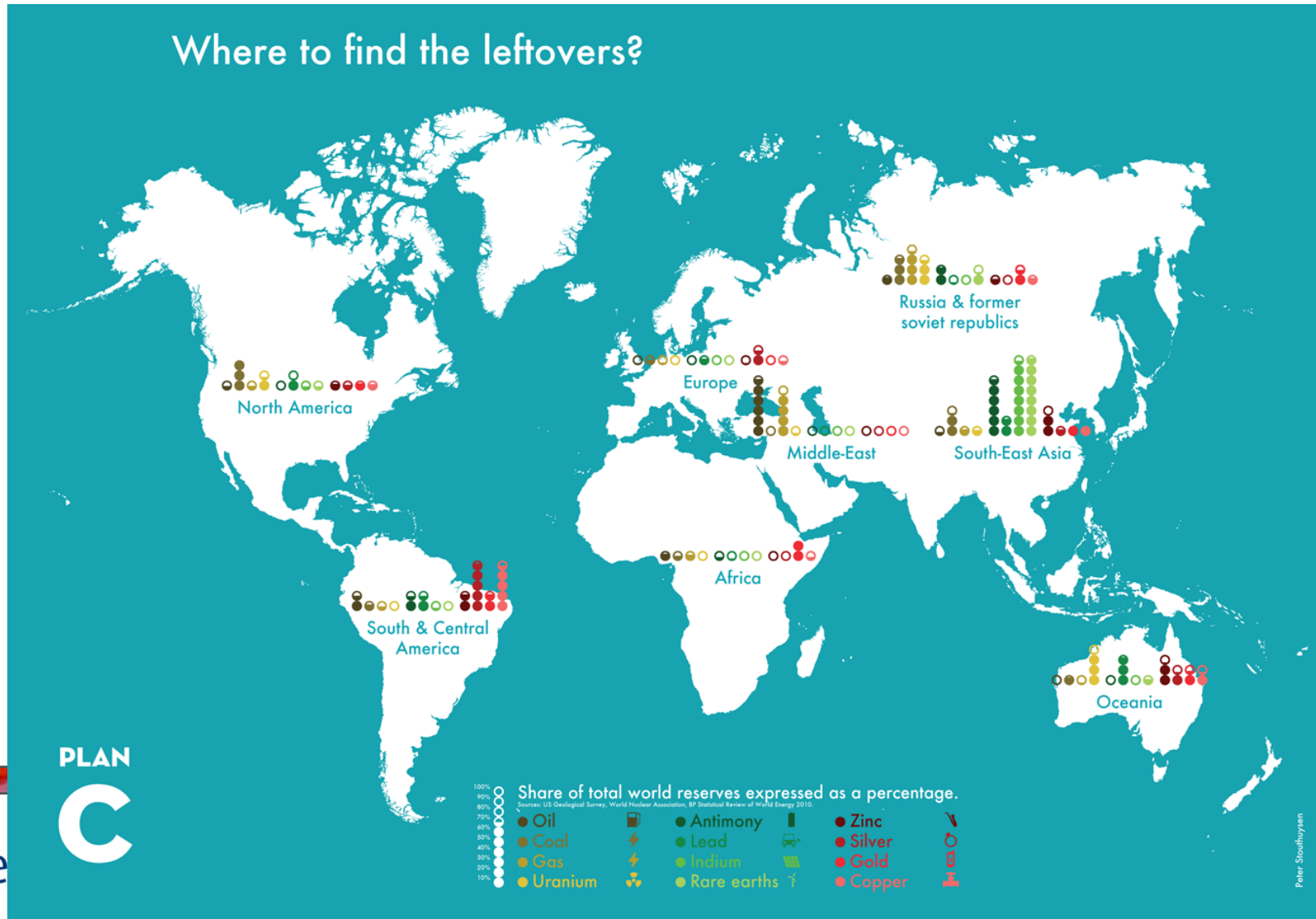
- Correlation between resource use and other environmental impacts
- Need for a more holistic view on technology and environment:
 - not only end-of-pipe
 - complete supply chain
 - preventive rather than clean-up
 - act pro-active through resource management
 - direct link with economic potential

Driver of industrial production/consumption: Resources



Driver of industrial production/consumption: Resources

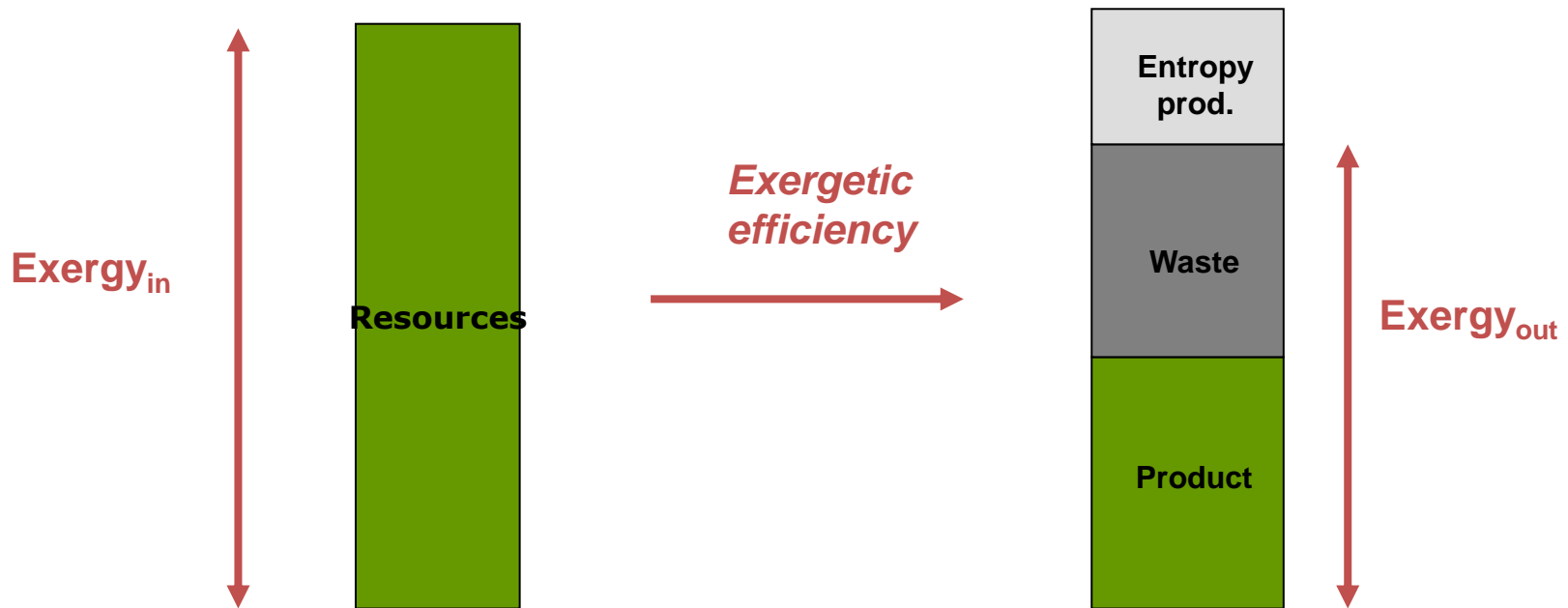
Where to find the leftovers?



What with the resources?

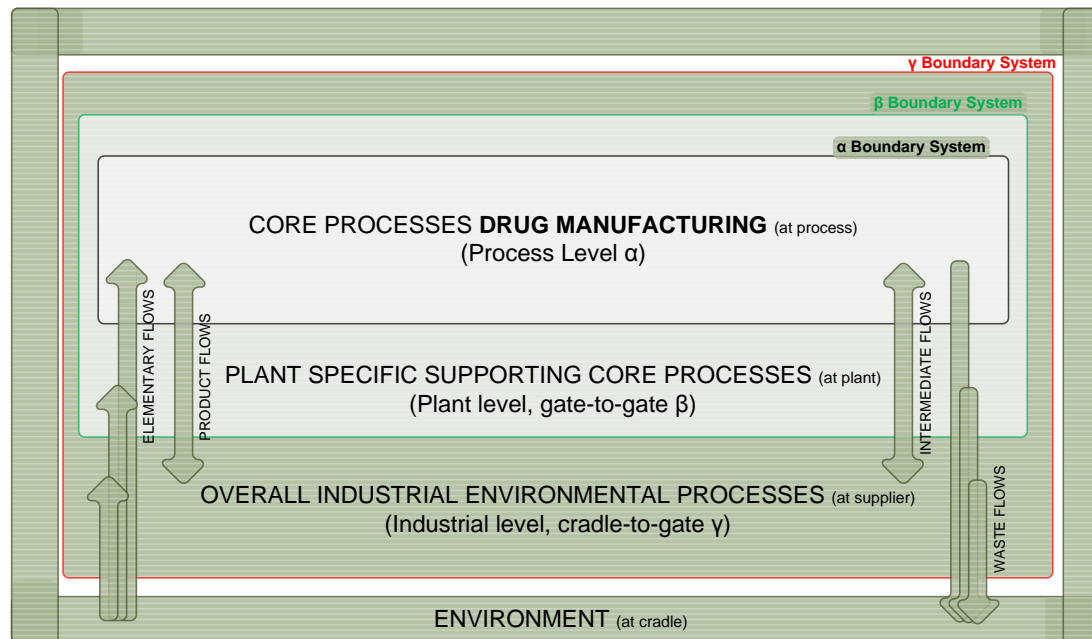
Exergy Analysis

- How to quantify all different kinds of resource? Energetic, physical resources?



Life Cycle Assessment – What with the resources? Exergetic LCA

- Combination of Process Analysis (EA) and Life Cycle Analysis (ELCA)
 - Identification, localization and reduction of environmental burdens



Life Cycle Assessment – What with the resources?

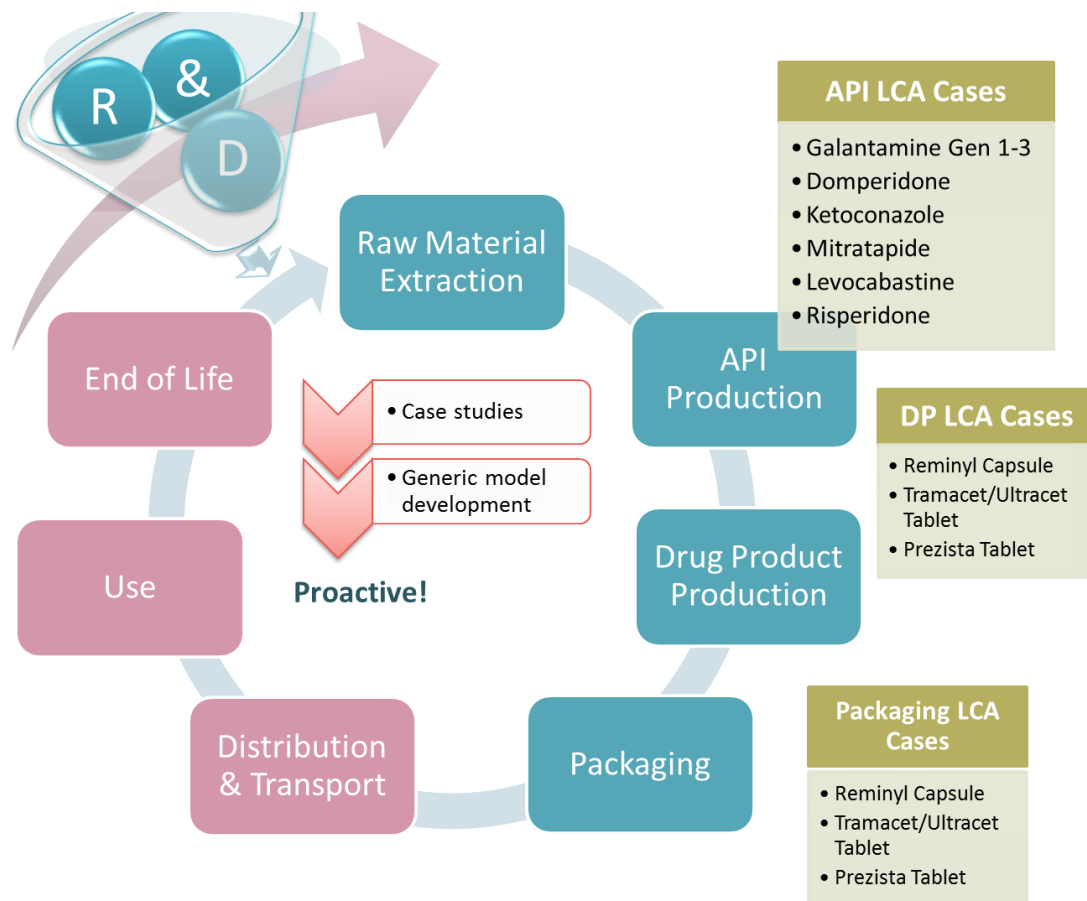
Exergetic LCA

- Main features
 - Universal and scientifically sound
 - Quantification of all physical resources
 - One single scale for all type of energy and materials
 - Quantifying resource efficiency at process, gate-to-gate & life cycle level
 - Identification of weaknesses & opportunities
 - Fingerprint of the extracted resources
- Disadvantages
 - Resource assessment rather than emissions assessment
 - Not easy to communicate

Past, current and future LCAs



Past, current and future Projects



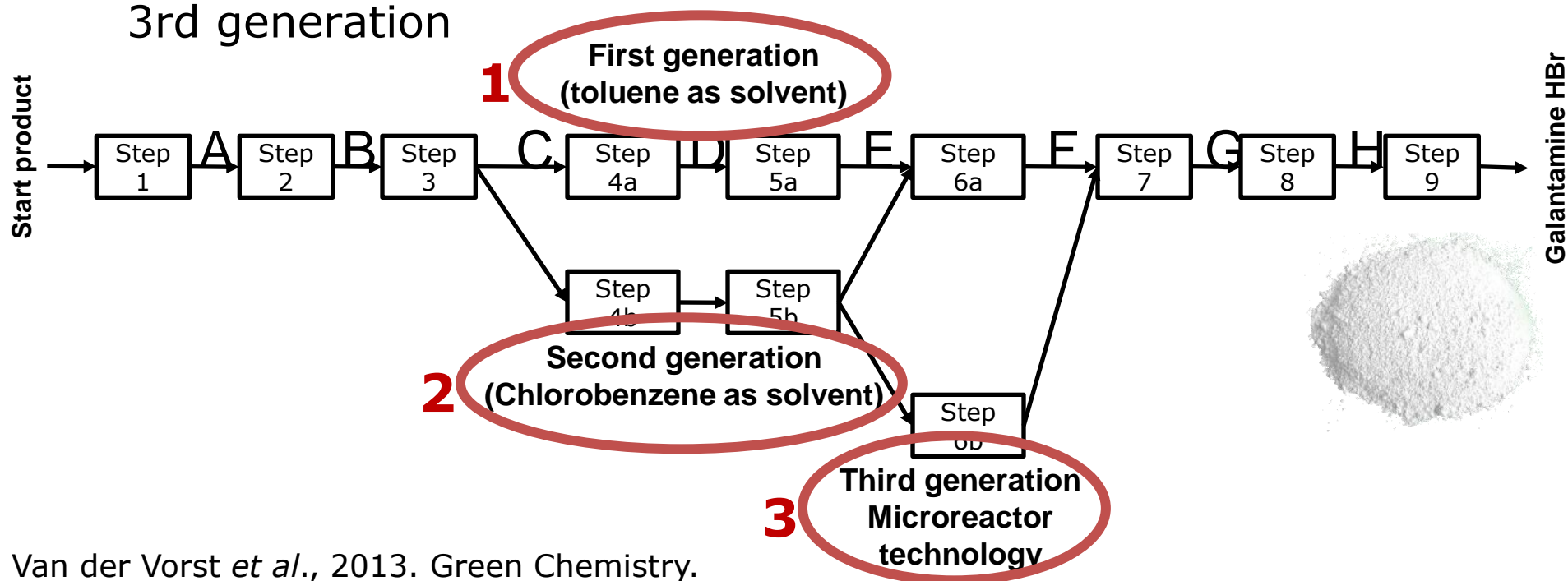
API ELCA Cases

- Assess environmental sustainability (“greenness”) and resource consumption of API synthesis steps of:
 - Domperidone (10 steps)
 - Ketoconazole (8 steps)
 - Levocabastine (8 steps)
 - Mitratapide (7 steps)
 - Risperidone (7 steps)
- 1-9 GJ_{ex}/mole API
- 65% of resource extraction of API production due to fossil resources at the cradle
- 45% of resource losses occur at JNJ plant Geel (BE), 55% through supply chain



API ELCA Cases: Galantamine generations

- Comparative environmental sustainability assessment of 3 generations of Galantamine
- +- 41% reduction in integral resource consumption 1st → 3rd generation



Van der Vorst *et al.*, 2013. Green Chemistry.

DP ELCA Cases

- Full life cycle evaluation of Galantamine.HBr (Reminyl®, prolonged release capsules)
- Batch versus continuous Drug Product (DP) Production? The case of Tramacet®
- Upscaling of R&D to manufacturing batch sizes in DP Production: impact on the resource footprint



DP ELCA Cases

Exergetic sustainability assessment of batch versus continuous wet granulation based pharmaceutical tablet manufacturing: a cohesive analysis at three different levels



De Soete *et al.*, 2013. Green Chemistry.



Green Chemistry

Cutting-edge research for a greener sustainable future

www.rsc.org/greenchem

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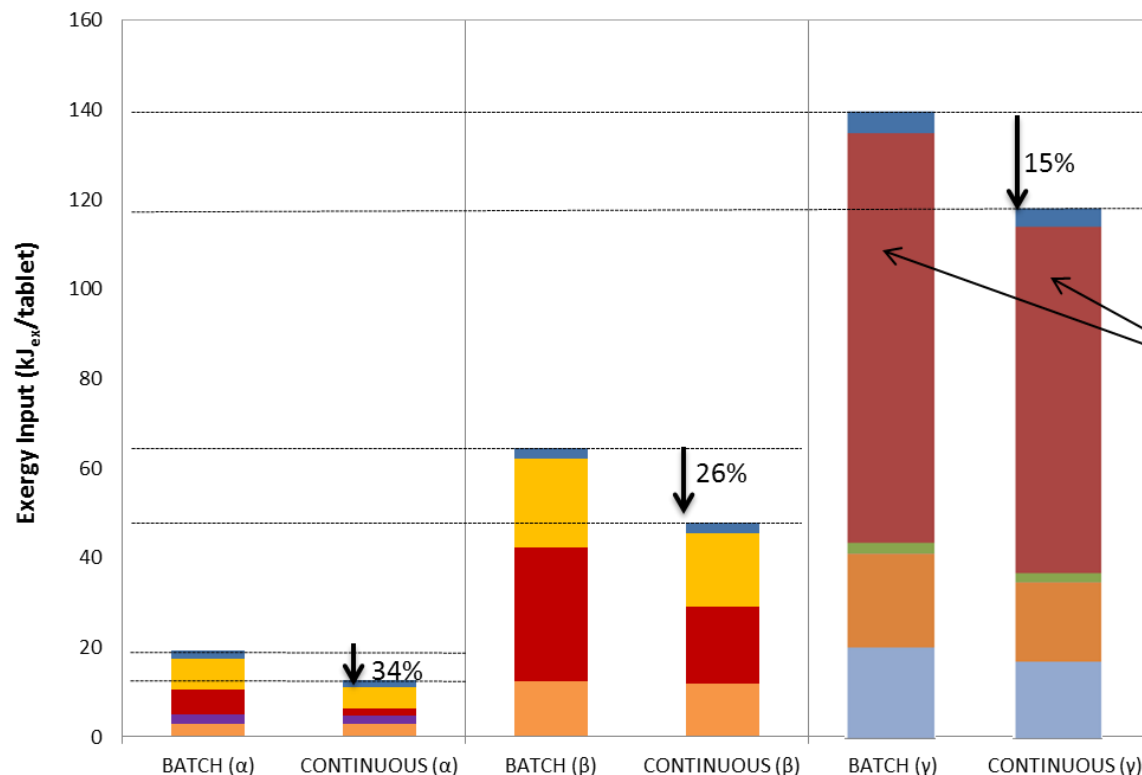
PAPER

Wouter De Soete *et al.*
Exergetic sustainability assessment of batch versus continuous wet granulation based pharmaceutical tablet manufacturing: a cohesive analysis at three different levels



1463-9262 (2013) 15:11;1-0

DP ELCA Cases



Functional Categories

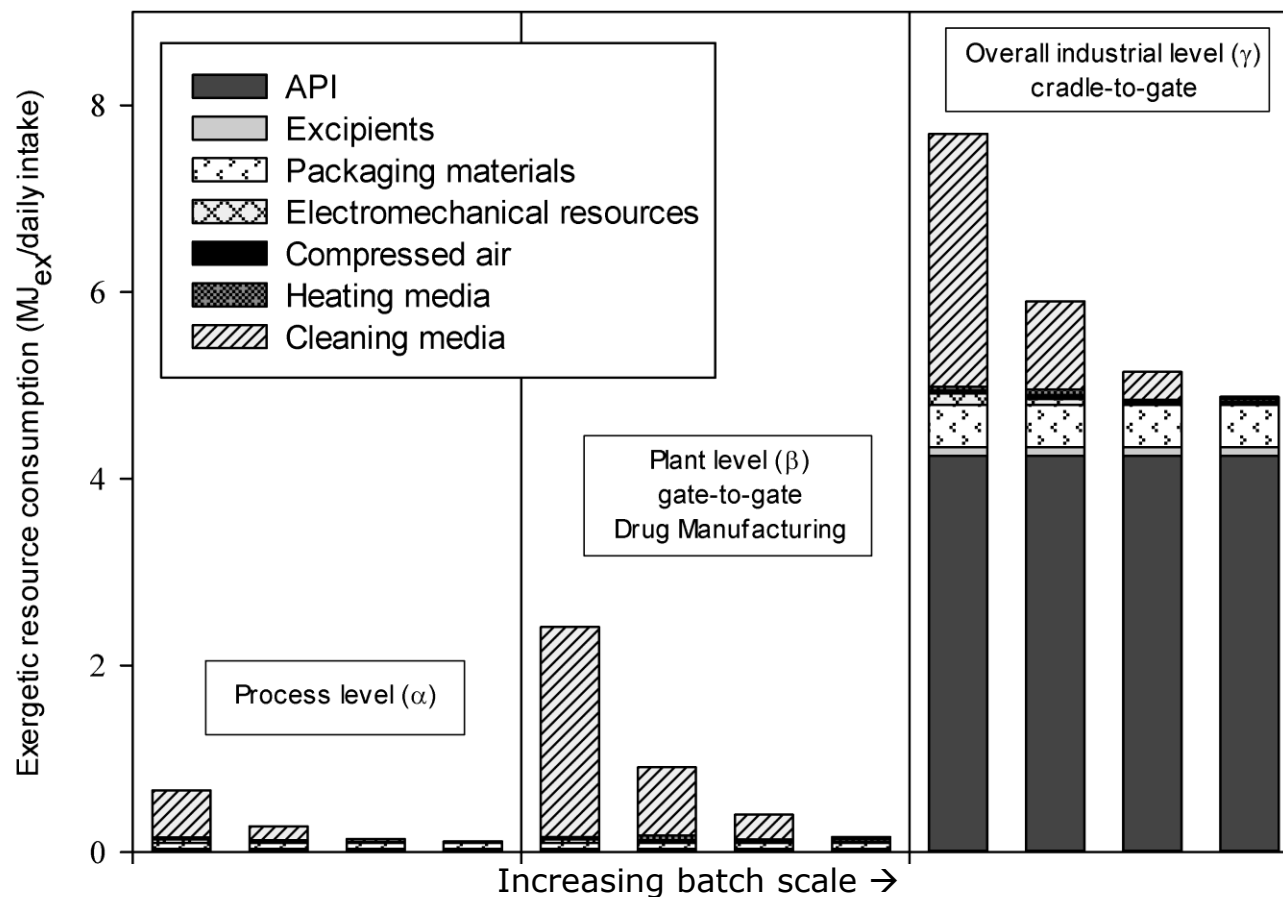
- Chemicals (Excipients)
- Electromechanical
- Heating media
- Compressed air
- Cleaning agents and disposal

Resource Categories

- Renewable resources other than biomass
- Fossil fuels
- Nuclear energy
- Metal ores
- Minerals and mineral aggregates
- Water resources
- Land occupation

- Tablet CEENE: 65% fossil, 15% water resources, 15% land occupation/biomass, 5% renewables resources other than biomass

DP ELCA Cases



Current and future projects

- Environmental sustainability assessment of Janssen Pharmaceutica catering and hospitality services



- Resource footprinting of biological technological production of Stelara®



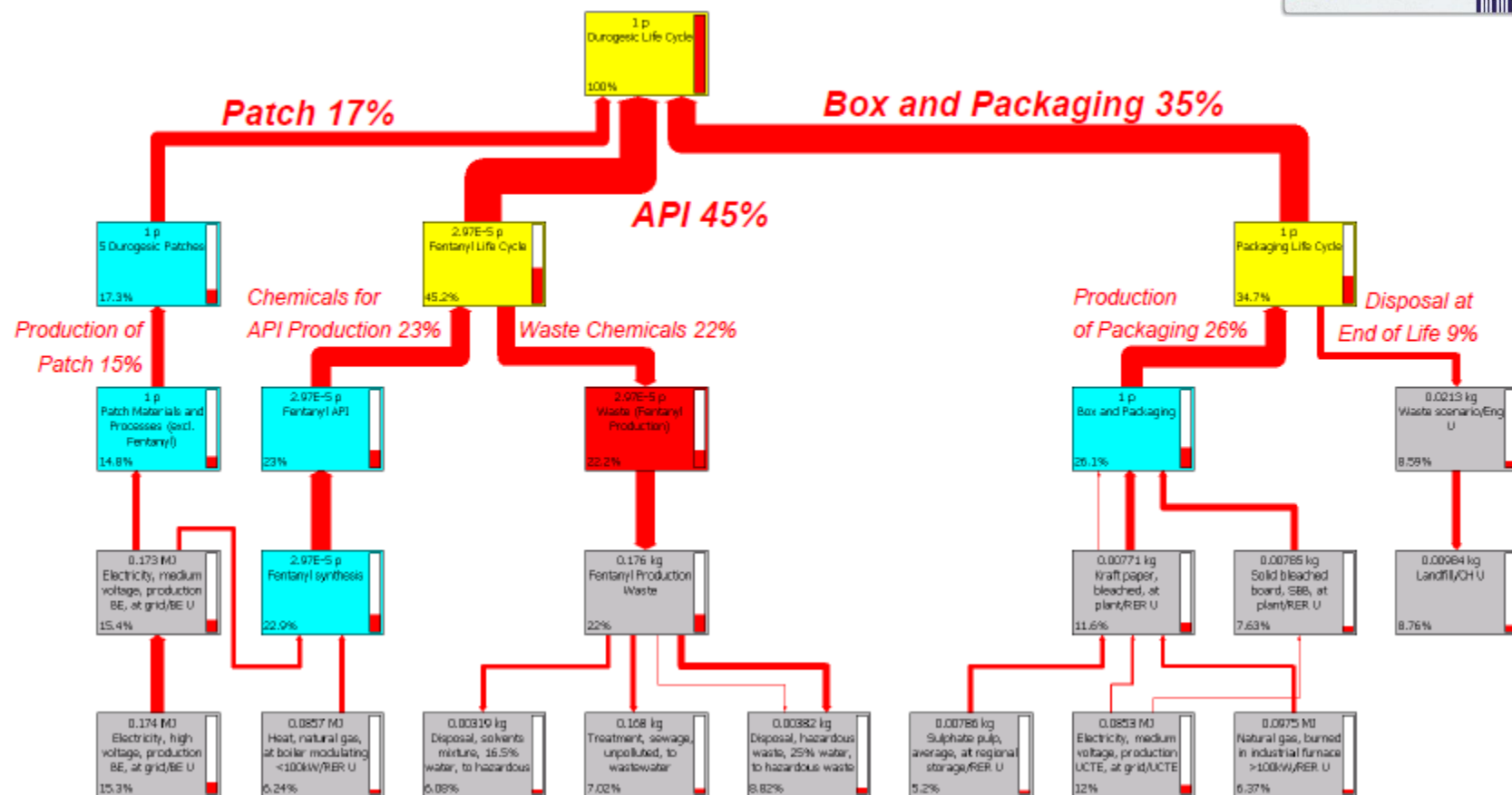
- In study: Balancing positive and negative human toxicity effects of pharmaceutical production processes
- Prezista TMC114

Carbon Footprinting

- Carbon Footprinting of Durogesic®
- Risperdal Consta® and Xeplion® Carbon Footprint



Carbon Footprinting





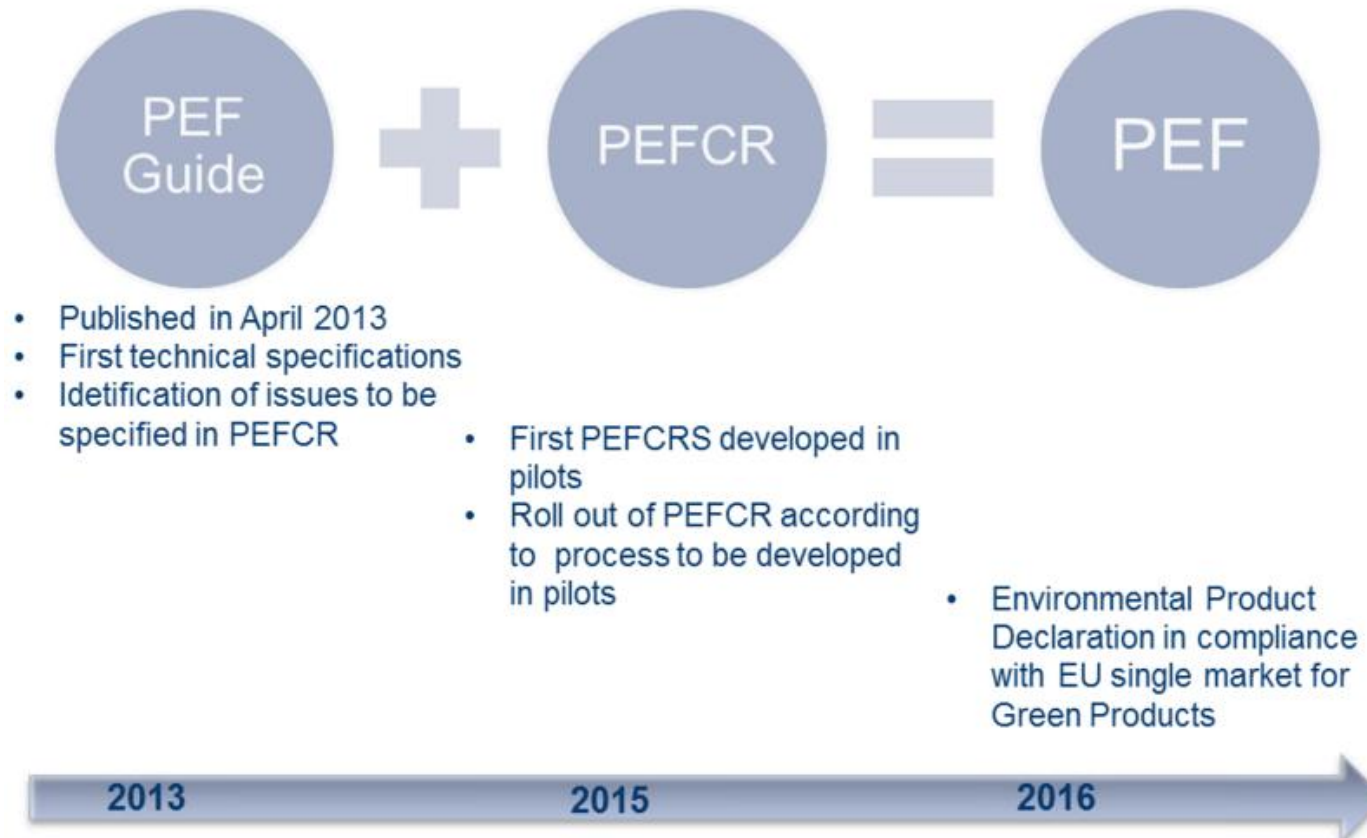
One step ahead – EU Prospects

One step ahead – EU Prospects

- ISO 14000 series
- ILCD Handbook (EU-JRC)
- Product Environmental Footprint (PEF)
Organization Environmental Footprint (OEF)
+ Product Category Rules
 - 14 impact categories
 - Take into account capital goods, infrastructure, linear depreciation
 - No cut-off criteria allowed anymore
 - What about land use? Soil Organic Matter (SOM); scarce data
→ CEENE

One step ahead – EU Prospects

Product Environmental Footprint Initiative of the EC



Q&A





Thank You !

Janssen Pharmaceutica

PDMS – Technical Operations - EHS²

